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UNITED STATES GOVERNMENT

M E M O R A N D U M

DATE: November 16, 1993

REPLY TO
ATTN OF: Robert Cleveland, SED, OET, 653-8169

SUBJECT: Item to be placed in Docket ET 93-62

TO: Secretary, FCC

Please place the attached letter from the Department of Health and Human Services, Food and Drug Administration, signed by L. Gill and dated November 10, 1993, in the record of ET Docket 93-62, "Guidelines for Evaluating the Environmental Effects of Radiofrequency Radiation." Four copies and the original letter are enclosed.

ENCLOSURES

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NOV 17 1993
FEDERAL COMMUNICATIONS COMMISSION
OFFICE OF THE SECRETARY

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
Rockville MD 20857

November 10, 1993

Mr. Thomas P. Stanley
Federal Communications Commission
2025 M Street, N.W., Rm. #7002
Washington, D.C. 20554

93-62

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OFFICE OF ENGINEERING AND TECHNOLOGY

Dear Mr. Stanley:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) appreciates the opportunity to comment on your Notice of Proposed Rule Making regarding human exposures to radiofrequency (RF) energy. We feel that the FCC should replace its present guidelines with most, but not all, of the material contained in the ANSI/IEEE C95.1-1992 standard.

We feel that the replacement by the FCC of the ANSI C95.1-1982 guidelines with most of the provisions of the ANSI/IEEE C95.1-1992 guidelines is appropriate and will provide a greater level of protection to the general public. One particularly useful provision in the 1992 guideline is the establishment of lower maximum permissible exposures for persons in "uncontrolled environments". Moreover, we especially concur in FCC's stated intent that "hand-held portable devices...must comply with the requirements specified for uncontrolled environments".

There is, however, one provision with which we must disagree. The ANSI/IEEE C95.1-1992 guideline is clearly founded on the concept that the maximum permissible rate of energy deposition (specific absorption rate, or SAR) in the human body is the fundamental, causative parameter. However, the concept of limiting the SAR induced in the body appears to be disregarded in one portion of the 1992 ANSI standard: a "low-power exclusion clause" that exempts certain RF devices from the provisions of the standard only because they emit less than a specified amount of power. Recent data from technical publications and other sources indicate that certain lower powered RF devices, such as hand-held, portable, two-way radios, cellular phones, and other personal communication devices can induce relatively high SARs in portions of the body of nearby persons. Indeed, some devices that meet the requirements of the low-power exclusion clause can induce SARs that exceed the local-SAR limits specified elsewhere in the same standard -- making the standard appear self-contradictory. Hence, we must recommend against FCC's adoption of this low-power exclusion clause.

With respect to the specific levels cited in the standard for Maximum Permissible Exposures and SARs, CDRH has in the past expressed concern about the 1992 guidelines. The standard, as written, lacks a full explanation of its basis. In our opinion, it is unclear what types of biological effects and exposure conditions are addressed by the standard. For example, very few research studies of long- term, low-level exposures of animals were included in the scientific rationale for the standard, despite the existence of animal studies that suggest an association between chronic low level exposures and acceleration of cancer development. Other studies have been published since finalization of the standard that strengthen this concern. In addition, there are insufficient studies of the health of humans who have been exposed to RF

for several years or more. Although the current state of scientific knowledge does not enable us to offer a specific alternative to the exposure levels in the new standard, we do not believe this standard addresses the issue of long-term, chronic exposures to RF fields. The relevance of such questions can only increase as the use of portable and hand-held devices grows. We, therefore, recommend that new research be closely monitored for possible evidence that the levels in the 1992 guideline may need to be reduced.

Finally, CDRH would like to address an issue concerning the measurement aspects of the proposed safety standard. This topic was raised in the FCC's request for comments on page 8, paragraph 17. Our experience with radiation protection personnel suggests that many of them have difficulty interpreting standards that require specialized measurements of RF exposure fields and SAR. We recommend that the FCC specifically endorse the procedures specified in a companion document (ANSI C95.3-1992). This document is "IEEE Recommended Practice for the Measurement of Potentially Hazardous Electromagnetic Fields - RF and Microwave". It addresses the proper selection and use of instrumentation for making specialized RF hazard-assessment measurements. We believe that compliance with the exposure standard should require proof of the precision and accuracy of measurements and instruments, using the definitions and principles specified in the C95.3-1992 document.

In conclusion, CDRH recommends approval of the Proposed Rule, with the exception of the exclusion clause for low power devices. In addition, we recommend that the scientific literature be closely monitored for possible evidence that the exposure levels cited by the new standard may need to be reduced. We look forward to a continued coordination of FCC and FDA activities aimed at protecting personnel from excessive exposures to RF fields and the resulting SARs and currents induced in the human body. In our view, the adoption of the 1992 ANSI standard furthers, but does not end our respective RF protection efforts.

Sincerely,

Lillian J. Gill

Lillian J. Gill, Interim Director
Office of Science and Technology
Center for Devices and Radiological Health